

We claim.

1. A hermetically sealed electrode assembly for an electrically assisted drug delivery device, comprising an anode assembly comprising a first electrode and a donor hydrogel containing epinephrine in electrical contact with the first electrode, wherein the hermetically sealed anode assembly is physically, chemically, electronically, electrochemically or microbiologically stable for at least 12 months at 25°C.
2. The electrode assembly of claim 1, wherein the epinephrine in the donor hydrogel degrades to no more than 90% of original levels for at least 24 months at 25°C.
3. The electrode assembly of claim 1, wherein the anode assembly is physically stable for at least 24 months at 25°C.
4. The electrode assembly of claim 1, wherein the anode assembly is chemically stable for at least 24 months at 25°C.
5. The electrode assembly of claim 1, wherein the anode assembly is electrochemically stable for at least 10 months at 25°C.
6. The electrode assembly of claim 1, wherein the anode assembly is physically, chemically, electronically, electrochemically and microbiologically stable for at least six months at 40°C.
7. The electrode assembly of claim 1, wherein the anode assembly is physically, chemically, electronically, electrochemically and microbiologically stable for at least 12 months at 30°C.
8. The electrode assembly of claim 1, wherein the donor hydrogel comprises a local anesthetic.
9. The electrode assembly of claim 8, wherein the local anesthetic is lidocaine.

10. The electrode assembly of claim 1, further comprising a cathode assembly comprising a second electrode and a return hydrogel in electrical contact with the second electrode, wherein the anode and cathode electrodes are attached to a backing.
11. The electrode assembly of claim 10, further comprising an electrically conductive anode trace attached to the backing and electrically connected to the first electrode and an electrically conductive cathode trace attached to the backing and electrically connected to the second electrode.
12. The electrode assembly of claim 11, wherein the anode and cathode traces are coated with a dielectric material.
13. The electrode assembly of claim 11, wherein the first and second electrodes and the anode and cathode traces are printed with silver/silver chloride-containing ink.
14. The electrode assembly of claim 10, wherein the first and second electrodes are silver/silver chloride electrodes.
15. The electrode assembly of claim 1, wherein the epinephrine in the donor hydrogel degrades to no more than about 95% wt. of original levels in 24 months at 25°C.
16. The electrode assembly of claim 1, the epinephrine in the donor hydrogel degrading to no more than about 94% wt. of original levels in 18 months at 25°C.
17. The electrode assembly of claim 1, wherein the hydrogel comprises polyvinyl pyrrolidone.
18. The electrode assembly of claim 17, wherein the hydrogel is about 17% wt. polyvinyl pyrrolidone.
19. The electrode assembly of claim 1, wherein the first electrode is a silver or a silver/silver chloride electrode.

20. The electrode assembly of claim 1, wherein the donor hydrogel contains an amount of sodium metabisulfite equal to or slightly greater than a minimal amount of sodium metabisulfite needed to scavenge oxygen in the packaged donor hydrogel for at least 24 months.
21. The electrode assembly of claim 20, wherein the donor hydrogel contains less than about 110% of the amount of sodium metabisulfite equal to a minimal amount of sodium metabisulfite needed to scavenge oxygen in the packaged donor hydrogel for at least 24 months.
22. The electrode assembly of claim 20, wherein the donor hydrogel contains about 101% of the amount of sodium metabisulfite equal to a minimal amount of sodium metabisulfite needed to scavenge oxygen in the packaged donor hydrogel for at least 24 months.
23. The electrode assembly of claim 1, wherein the donor hydrogel comprises from about 2% wt. to about 12% wt. lidocaine and from about 0.001% wt. to about 0.3% wt epinephrine.
24. The electrode assembly of claim 23, wherein the donor hydrogel has a volume of about 1ml and comprises about 100 mg lidocaine HCl and about 1.05 mg epinephrine bitartrate.
25. The electrode assembly of claim 24, wherein the donor hydrogel is about 40 mil \pm 5 mil thick.
26. The electrode assembly of claim 1, wherein the donor hydrogel comprises lidocaine HCl and epinephrine bitartrate in about a 70-125:1 mass ratio.

27. The electrode assembly of claim 1, the donor hydrogel further contains lidocaine and one or more of parabens, sodium metabisulfite, a chelating agent, citric acid, glycerin and sodium chloride.
28. The electrode assembly of claim 1, wherein the donor electrode is prepared by contacting a solution containing the lidocaine and the epinephrine with an unloaded hydrogel containing from about 0.001% wt. to about 1.0% sodium chloride.
29. The electrode assembly of claim 1, packaged under an inert atmosphere.
30. The electrode assembly of claim 29, wherein the inert gas is nitrogen.
31. An electrode assembly for an electrically assisted drug delivery device packaged in an inert atmosphere in a hermetically sealed container, the electrode assembly comprising:
- (a) a backing;
 - (b) a first silver or silver/silver chloride electrode attached to the backing and a donor hydrogel comprising polyvinyl pyrrolidone and containing lidocaine and epinephrine in electrical contact with the first electrode;
 - (c) a second silver or silver/silver chloride electrode attached to the backing and a return hydrogel in electrical contact with the second electrode;
 - (d) an electrically conductive silver or silver/silver chloride anode trace attached to the backing and in electrical contact with the first electrode;
 - (e) an electrically conductive silver or silver/silver chloride cathode trace attached to the backing and in electrical contact with the second electrode; and
 - (f) a dielectric layer coating at least a portion of the anode and cathode traces,

wherein the donor hydrogel contains an amount of sodium metabisulfite equal to or slightly greater than a minimal amount of sodium metabisulfite needed to scavenge oxygen in the donor hydrogel for at least 10 months and an amount of salt sufficient to prevent electrode corrosion during or after loading of the hydrogel reservoir, wherein the first and second electrodes and the anode and cathode traces are printed, and wherein the anode assembly is stable for at least 10 months at 25°C.

32. A method for preparing a shelf-stable electrode assembly for electrically assisted delivery of a local anesthetic and vasoconstrictor to a patient, the electrode assembly comprising an unloaded hydrogel reservoir in electrical contact with a silver-silver chloride electrode, the unloaded hydrogel reservoir containing an amount of salt sufficient to prevent electrode corrosion during or after loading of the hydrogel reservoir; the method comprising:

- (a) loading the unloaded hydrogel reservoir with a loading solution containing lidocaine and epinephrine; and
- (b) packaging the assembly in an inert atmosphere in a hermetically sealed container.

33. The method of claim 32, wherein, prior to the loading, the loading solution is absorbed into an absorbent pad attached to a releasable liner configured to cover the hydrogel reservoir, and the releasable liner is attached to the electrode assembly with the absorbent pad contacting the hydrogel reservoir, thereby contacting the loading solution with the hydrogel.

34. An electrode assembly for an electrically assisted drug delivery device, comprising a first electrode and a donor hydrogel comprising lidocaine and epinephrine

in electrical contact with the first electrode, wherein the electrode assembly is electrically stable, physically stable and chemically stable for at least 12 months at 25°C when the anode assembly is hermetically sealed.

35. A packaged electrode assembly for an electrically assisted drug delivery device, comprising a hermetically sealed container and an electrode assembly sealed within the container, the electrode assembly comprising a first electrode and a donor polyvinyl pyrrolidone comprising hydrogel comprising lidocaine and epinephrine in electrical contact with a silver/silver chloride first electrode, wherein the packaged electrode assembly is electrically stable, physically stable and chemically stable for at least 12 months at 25°C when the anode assembly is hermetically sealed.

36. The packaged electrode assembly of claim 35, wherein the donor hydrogel contains an amount of sodium metabisulfite equal to or slightly greater than a minimal amount of sodium metabisulfite needed to scavenge oxygen in the packaged donor hydrogel for at least 24 months.

37. A packaged electrode assembly for an electrically assisted drug delivery device, comprising a hermetically sealed electrode comprising an anode assembly, the anode assembly comprising a first electrode and a donor hydrogel containing a vasoconstrictor, an anesthetic and pharmaceutically acceptable excipients in electrical contact with the first electrode, wherein the electrode assembly is physically, chemically, electronically, electrochemically or microbiologically stable for at least 12 months at 25°C.

38. The packaged electrode assembly of claim 37, wherein the vasoconstrictor is one of epinephrine and phenylephrine.

39. The packaged electrode assembly of claim 37, wherein the anesthetic is selected from the group consisting of amide type anesthetics, ester type anesthetics, bupivacaine, butanilcaine, carticaine, cinchocaine/dibucaine, clibucaine, ethyl parapiperidino acetylaminobenzoate, etidocaine, lidocaine, mepivacaine, oxethazaine, prilocaine, ropivacaine, tolycaine, trimecaine, vadocaine, amylocaine, cocaine, propanocaine, esters of metaaminobenzoic acid, clormecaine, proxymetacaine, esters of paraaminobenzoic acid, amethocaine, benzocaine, butacaine, butoxycaine, butyl aminobenzoate, chloroprocaine, oxybuprocaine, parethoxycaine, procaine, propoxycaine, tricaine, bucricaine, dimethisoquin, diperodon, dyclocaine, ethyl chloride, ketocaine, myrtecaine, octacaine, pramoxine and propipocaine.

40. The packaged electrode assembly of claim 37, wherein the anesthetic is one of bupivacaine, butacaine, chloroprocaine, cinchocaine, etidocaine, mepivacaine, prilocaine, procaine, ropivacaine and tetracaine.

41. The packaged electrode assembly of claim 37, wherein the anesthetic is one of bupivacaine, etidocaine, mepivacaine, ropivacaine and prilocaine.

42. The packaged electrode assembly of claim 37, wherein the anesthetic is lidocaine.

43. The packaged electrode assembly of claim 42, wherein donor hydrogel comprises between about 2% wt. to about 12% wt. lidocaine.

44. The packaged electrode assembly of claim 42, wherein donor hydrogel comprises between about 5% wt. to about 12% wt. lidocaine.

45. The packaged electrode assembly of claim 42, wherein donor hydrogel comprises between about 8% wt. to about 12% wt. lidocaine.
46. The packaged electrode assembly of claim 37, wherein the electrode assembly is physically, chemically, electronically, electrochemically or microbiologically stable for at least 18 months at 25°C.
47. The packaged electrode assembly of claim 37, wherein the electrode assembly is physically, chemically, electronically, electrochemically or microbiologically stable for at least 10 months at 25°C.
48. The packaged electrode assembly of claim 37, wherein the electrode assembly is physically, chemically, electronically, electrochemically or microbiologically stable for at least 36 months at 25°C.
49. The packaged electrode assembly of claim 37, wherein the electrode assembly is physically, chemically, electronically, electrochemically or microbiologically stable for at least 48 months at 25°C.
50. The packaged electrode assembly of claim 37, wherein the donor hydrogel comprises from about 0.001% wt. to about 0.3% wt. epinephrine.
51. The packaged electrode assembly of claim 37, wherein the donor hydrogel comprises from about 0.01% wt. to about 0.3% wt. epinephrine.
52. The packaged electrode assembly of claim 37, wherein the donor hydrogel comprises from about 0.075% wt. to about 0.125% wt. epinephrine.

53. The packaged electrode assembly of claim 37, wherein the donor hydrogel comprises from about 0.005% wt. to about 0.1% wt. sodium metabisulfite.
54. The packaged electrode assembly of claim 37, wherein the donor hydrogel comprises from about 0.025% wt. to about 0.075% wt. sodium metabisulfite.
55. The packaged electrode assembly of claim 37, wherein the donor hydrogel comprises from about 0.01% wt. to about 0.1% wt. sodium chloride.
56. The packaged electrode assembly of claim 37, wherein the donor hydrogel comprises polyvinylpyrrolidone.
57. The packaged electrode assembly of claim 37, wherein the first electrode is a silver or silver/silver chloride electrode.
58. The packaged electrode assembly of claim 37, wherein the first electrode is a printed silver or silver/silver chloride electrode.
59. The packaged electrode assembly of claim 37, wherein the electrode is packaged in an inert atmosphere.
60. The packaged electrode assembly of claim 59, wherein the inert atmosphere comprises nitrogen.
61. The packaged electrode assembly of claim 37, wherein the donor hydrogel is a polyvinylpyrrolidone hydrogel comprising lidocaine, epinephrine, sodium metabisulfite, citric acid, sodium chloride, a chelating agent, parabens and glycerin and the electrode is packaged in an inert atmosphere.

62. A packaged electrode assembly for an electrically assisted drug delivery device, comprising a hermetically sealed electrode packaged in an inert atmosphere, the electrode comprising an anode assembly, the anode assembly comprising a first electrode and a polyvinylpyrrolidone donor hydrogel in electrical contact with the first electrode, the hydrogel containing lidocaine, epinephrine, sodium metabisulfite, citric acid, sodium chloride, parabens and glycerin, wherein the electrode assembly is physically, chemically, electronically, electrochemically or microbiologically stable for at least 12 months at 25°C.

63. A transdermal patch comprising epinephrine that is stable at 25°C for at least about 24 months.

64. An electrotransport reservoir comprising epinephrine that is stable at 25°C for at least about 24 months.

65. A packaged transdermal drug delivery device, comprising a hermetically sealed polyvinylpyrrolidone hydrogel packaged in an inert atmosphere, the hydrogel containing lidocaine, epinephrine, sodium metabisulfite, citric acid, sodium chloride, a chelating agent, parabens and glycerin, wherein the electrode assembly is physically, chemically or microbiologically stable for at least 12 months at 25°C.

66. The packaged electrode assembly of claim 65, wherein donor hydrogel comprises between about 2% wt. to about 12% wt. lidocaine.

67. The packaged electrode assembly of claim 65, wherein donor hydrogel comprises between about 5% wt. to about 12% wt. lidocaine.

68. The packaged electrode assembly of claim 65, wherein donor hydrogel comprises between about 8% wt. to about 12% wt. lidocaine.

69. The packaged electrode assembly of claim 65, wherein the electrode assembly is physically, chemically, electrochemically, electrically or microbiologically stable for at least 18 months at 25°C.

70. The packaged electrode assembly of claim 65, wherein the electrode assembly is physically, chemically, electrochemically, electrically or microbiologically stable for at least 24 months at 25°C.

71. The packaged electrode assembly of claim 65, wherein the electrode assembly is physically, chemically, electrochemically, electrically or microbiologically stable for at least 36 months at 25°C.

72. The packaged electrode assembly of claim 65, wherein the electrode assembly is physically, chemically, electrochemically, electrically or microbiologically stable for at least 48 months at 25°C.

73. The packaged electrode assembly of claim 65, wherein the donor hydrogel comprises from about 0.001% wt. to about 0.3% wt. epinephrine.

74. The packaged electrode assembly of claim 65, wherein the donor hydrogel comprises from about 0.01% wt. to about 0.3% wt. epinephrine.

75. The packaged electrode assembly of claim 65, wherein the donor hydrogel comprises from about 0.075% wt. to about 0.125% wt. epinephrine.

76. The packaged electrode assembly of claim 65, wherein the donor hydrogel comprises from about 0.005% wt. to about 0.1% wt. sodium metabisulfite.

77. The packaged electrode assembly of claim 65, wherein the donor hydrogel comprises from about 0.025% wt. to about 0.075% wt. sodium metabisulfite.

78. The packaged electrode assembly of claim 65, wherein the donor hydrogel comprises from about 0.01% wt. to about 0.1% wt. sodium chloride.